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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,425	11/13/2003	Frank D. Lee	EPT-001C1	9956

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EXAMINER	
LIN, JERRY	

ART UNIT	PAPER NUMBER
1631	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/712,425	LEE ET AL.	
	Examiner	Art Unit	
	Jerry Lin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20,22-35 and 126-132* is/are pending in the application.

4a) Of the above claim(s) *11,15,26-30 and 128* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,12-14,16-20,22-25,31-35,126,127 and 129-132* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 November 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 8, 2007 has been entered.

Applicants' arguments, filed May 8, 2007, have been fully considered and they are deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are newly applied. They constitute the complete set presently being applied to the instant application.

Status of the Claims

Claims 1-10, 12-14, 16-20, 22-25, 31-35, 126, 127, and 129-132 are under examination.

Claims 11, 15, 26-30, and 128 are withdrawn as being directed toward an unelected invention.

Claims 21, 36-125 are cancelled (claims 37-125 are drawn to a non-elected invention).

Sequence Rules Compliance

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). Such sequences are present throughout the drawings as well as throughout the specification. However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because these sequences are not followed by a sequence identifier (SEQ ID NO:X). Applicants are given the same response time regarding this failure to comply as that set forth to respond to this office action. Applicants are reminded that it is required that SEQ ID Nos be amended into the specification at each sequence, and that when a sequence is presented in a drawing regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings. Failure to comply with these requirements may result in ABANDONMENT of the application under 37 CFR 1.821(g).

Drawings

3. The drawings are objected to because the drawing filed on November 13, 2003 are not legible. It is difficult to read the sequences on Figures 1 and 2 because the figures have a great deal of background noise. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the

figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. It is noted the color drawings were submitted on November 13, 2003. Color photographs and color drawings are not accepted unless a petition filed under 37 CFR 1.84(a)(2) is granted. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

> The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37 CFR 1.84(b)(2).

Claim Rejections - 35 USC § 112, 1st Paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10, 12-14, 16-20, 22-25, 31-35, 126, 127, 129-132 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for peptide fragments bound to a capture agent with a site available for a secondary capture agent, does not reasonable provide enablement for peptide fragments with a separate site unavailable for a secondary capture agent upon binding of the first capture agent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary – without a site for the secondary capture agent, one of ordinary skill in the art would have to develop a new type of secondary capture agent which would require a great deal of

experimentation; (2) the amount of direction presented – the specification does not teach using any new types of secondary capture agents; (3) the presence or absence of working examples – there are no examples with new types of secondary capture agents; (4) the nature of the invention – the invention is directed to a combination of well-known techniques for detecting the presence and location of post-translational modification; (5) the state of the prior art – it is known in the prior art that a secondary capture agent requires a site to bind to for detection; (6) the relative skill of those in the art – the skill in the biological sciences is high; (7) the predictability or unpredictability of the art – the art is unpredictable; (8) the breadth of the claims – the instant claims are drawn to peptide fragments of any size. Upon consideration of the Applicant's comments as well as considering the factors above, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The instant claims are drawn to a method of computationally analyzing an amino acid sequence of a target protein to identify one or more candidate sites for a post-translational modification, computationally identifying fragments that would result from a treatment wherein the fragments have a post-translational modification site that is separate from a proteome epitope tag (PET) that is unique to the fragment in the sample, generating a capture agent that binds to the (PET) and immobilizing the capture agent to a support, subjecting the target protein to the treatment and contacting the resulting fragments to the capture agent, and detecting the presence or absence of

the post-translational modification on the fragment by using a secondary capture agent specific for the post-translational modification.

In the Applicant's response on pages 10 to 11, the Applicants state that a "peptide length of 5-12 amino acids would create significant problems for binding of a second antibody, as the capture antibody occupies most or all of the only available epitope on such a small peptide." According to Applicants, the peptide fragment must be of a certain length in order to accommodate the binding of both the capture agent and a secondary capture agent. However, the instant claims make no mention of this requirement. Rather, the instant claims are generally drawn to a peptide fragment with a PET and a separate post-translational modification. As claimed, these peptide fragments would include those that are less than 12 amino acids in length. It is noted that in claim 8, specific lengths of PET that are greater than 12 amino acids are recited. However, step 3 of claim 1 recites that the capture agents specifically bind to the PET. According to step 3 of claim 1, the entire PET is occupied by the capture agent and leaves nothing for the secondary capture agent to bind, although the PET may be greater than 12 amino acids. Thus one of ordinary skill in the art would have to conduct undue experimentation in order to create secondary capture agents that bind to small peptides.

Claim Rejections - 35 USC § 112, 2nd Paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10, 12-14, 16-20, 22-25, 31-35, 126, 127, and 129-132 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Instant claim 1 recites in line 4 the limitation of "candidate sites." However, in line 7, the claim refers to a "potential post-translational modification site". It is unclear if the "potential post-translational modification site" is intended to refer to the "candidate sites" or some other site. Furthermore, since the potential post-translational modification site is in the singular form, it is unclear which of the candidate sites the potential post-translational modification site is referring. Clarification via clearer claim language is requested.

Claims 4 and 7 recite the limitation "said step of analyzing computationally analyzing amino acid sequences" in line 1 and 2. There is insufficient antecedent basis for this limitation in the claim. The instant claim refers to claim 1, however, claim 1 only conducts the step of computationally analyzing an amino acid sequence. Instant claim 1 does not computationally analyzing multiple sequences. Thus, it is unclear to which step claim 4 is referring.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:00-6:30, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JL/

/Shubo (Joe) Zhou/

SHUBO (JOE) ZHOU, PH.D.
PRIMARY EXAMINER